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EXAMINER	
ALI, SHUMAYA B	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	**Application No.** 10/681,076	**Applicant(s)** RESNIC, DANIEL	
	Examiner SHUMAYA B. ALI	**Art Unit** 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2006*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-20* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

In response to the office action mailed on 5/4/06, Applicant has amended claims 1-5, 8, 11, 13, and 16. Claims 21-26 are previously cancelled. Currently claims 1-20 are pending.

Claim Objections

Claim 5 is objected to because of the following informalities: applicant is suggested to use where by instead of "such that" in line 2.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specification with respect to figure 8 notes a piloting assembly device can be used to place the condom in the vagina. Thus, "without...piloting assembly device" in line 3 is new matter. In claim 4 "collar dos not contain any …straps" is new matter since figure 4 shows collar 2 with strap 3.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It has been noted that Applicant uses human body as reference points to describe claimed subject matter, which is indefinite. For example, in claim 1 lines 14 and 15 "elastomeric material surrounds the penis", in claim 10 lines 4 and 5 "the strap is harnessed snuggly around the scrotum", and in clam 11 lines 6 and 7 "the strap is stretched around the testicles" are some of the indefinite cases where human body is used as a reference point to describe claimed subject matter. Applicant is strongly suggested to use whereby clauses or adapted to language to describe body parts with respect to claimed structures in all appropriate claims.

In claim 1, line 1 “a thick walled, universal, unisex, safety device” is indefinite. It is not clear whether the invention is condom or the safety device. The second "comprising" in line 3 is indefinite since it is not clear whether safety device or the condom comprising the limitation after the recitation of second comprising. In line 6 “defining an open proximal end and a closed distal end” is indefinite. This limitation is repeated and does not further limit the open proximal end and closed distal end cited in line 3. In line 6 the material is defined as "stretchable" and in line 10 the material is redefined as "superstretachable", which is considered improper because the specification does not clearly state that the material is both stretchable and superstretchable. In line 10 "non-burstable" is indefinite. Condoms made from soft pliant latex elastomeric material can be burstable depending on how far the material is stretched and how much force is applied. It is not clear what structure in the claimed condom makes it non-burstable. In line 9 “such as" is indefinite. It is not clear what other organ is referred by the term "such as". In line

12 "or other" is indefinite. It is not clear what material is limited by the term "or other". In line 12 "combinations and derivatives thereof" is indefinite. Specification does not support that condom can be made from in combination of material listed in line 11-13. In lines 15 and 16 “sufficiently large diameter” is indefinite since the ranges of diameter limited by the term “sufficiently large” is not clear.

In claim 2 line 2 “thick enough” is indefinite. What size is thick or thick enough is not clear.

In claim 3 line 8 and in claim 9 line 4, “more readily” is indefinite. To what degree the condom can be more readily retained is unclear.

In claim 4 line 2 "other metal" is indefinite. It is not clear what other metal structure/material is limited by the term "other metal".

In claim 5 line 4 “loose fit around the penis” is indefinite. Since the size of penis may vary between individuals, it is not clear how the loose fit can be universal.

In claim 8 line 11, “or comparable combination” is indefinite. It is not clear what materials are being limited by "comparable combination".

In claim 10 line 2 “the closed distal end” is indefinite. Said recitation does not further limit closed distal end of claim 1. “The strap’ in line 4, “the collar” and “the seminal reservoir or reservoirs”, “the graduated diameter” in line 6 lack antecedent basis.

In claim 12 line 2 "rigid enough" is indefinite. What degree of rigidity is limited by "rigid enough" is not clear.

In claim 13 lines 3 "the collar" lacks antecedent basis.

In claim 18 lines 3 "piloting assembly device comprising: said safety condom" is indefinite. Piloting assembly and condom are two distinct structures; it is not clear how the piloting assembly can comprise the condom.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,2,6,7 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reddy US 5,168,881.

As to claim 1, Reddy discloses a condom comprising universal, unisex, safety device (col.1 lines 21-26) for protecting against communicable diseases transmitted by the exchange of bodily fluids and for preventing unwanted pregnancy (col.8 lines 36-38), comprising: soft, pliant, stretchable wall material (elastic/silicon elastomer is considered soft, pliant and stretchable material, see col.7 lines 12-19), a closed distal end (23,32, 61,71), an open (24,34,64,74), proximal end (closed distal end and open proximal end is also taught in col.9 lines 5-7), and a cylindrical wall section (22,33,66,77), where the condom is generally an elastic (col.7 line 13), tubular sheath of longitudinal axis with an inside and outside surface (structures 22,33,66, and 77 are tubular sheath with hollow inside surface and outside surface), having a generally phallic shape (structures 22,33,66,and 77 are phallic shape), wherein the tubular sheath is adapted to receive a male sex organ via the open, proximal end (col.3 lines 28-33), and additionally being adapted to be inserted into a sexual orifice of a passive partner such as a vagina (as shown in fig.3) and an anus (col.2 lines 53-66 and col.3 lines 28-33), whereby said tubular sheath is adapted to provide soft, natural tactile sensation (col.3 lines 60 and 61); wherein, where the condom is constructed from an elastomeric material (col.7 lines 13-19) surrounds the penis completely enclosed (col.3 lines 28-33), tubular sheath having a sufficiently large diameter (col.9 lines 13-16 cites diameter of 1-4 inches, which is considered sufficiently large diameter for receiving a small size male sex organ), wherein movement of the penis is made possible within the condom during coitus (col.3 lines 48-54), whereby fluid communication is prevented between the interior and the exterior thereof (preventing fluid communication from the exterior is an inherent function of condom), and where no modification to the condom is required for use by either an active or passive wearer (once the condom is put on over the male sex organ, the condom does not require modification). Reddy inherently discloses "super stretchable" elastomeric material (elastic/silicon elastomer is considered super stretchable, see col.7 lines 12-19). Reddy inherently discloses "non burstable" (elastomeric condom can be non burstable, for example, when not stretched. Bursting nature would depend on duration of use and how often and at what force the elastomeric wall is being stretched).

Although Reddy discloses "thin" walled condom (col.7 line 12), Reddy teaches the thin walled condom can have varying thickness (col.7 lines 16-19). Therefore, Reddy's condom can be made with thick wall construction. Reddy further teaches condom construction material can be synthetic material such as polyurethane, polyvinylchloride, silicone elastomer, etc. (col.7 lines 14-16). These construction materials read on semi-rigid wall material selected from a group consisting of polymers, USP class six thermoplastic elastomer (TPE), silicone rubber, latex or other semi-rigid, soft, pliant, stretchable, biocompatible material or combinations and derivatives thereof. Reddy however is silent on "shape retaining" wall. However, thick walled condom is well capable of retaining its shape, therefore would not require the condom to be rolled out over the male sex organ to function.

As to claim 2, Reddy's thick wall and semi-rigid nature of the condom is thick enough to allow a passive sexual partner to insert the condom into a vagina or anus without assistance from an active sexual partner or piloting assembly device.

As to claim 6, Reddy discloses where the condom comprises a generally tubular shape-retaining body, and has a first means (27, 37, and 75) for retaining and securing to an active male wearer during intercourse, and a second means (25, 35, 64, and 74) for retaining and securing within the orifice of a passive wearer during intercourse.

As to claim 7, Reddy discloses the second means for retaining and securing within the orifice of a passive wearer during intercourse is a collar (25,35, 64,74,112), where the collar extends outwardly as a contiguous, shield circumferentially formed around the longitudinal axis of the shape-retaining, tubular sheath of the condom.

As to claim 12, Reddy's thick wall and shape retaining condom and material construction of condom as applied for claim 1 makes the condom rigid enough to accept a non-erect male sex organ into its open, proximal end.

Claims 3-5, 9, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy US 5,168,881 in view of Schwartz US 5,513,652.

As to claim 3, Reddy discloses a collar (25,35,74,112) extending outwardly as a contiguous shield circumferentially formed around the longitudinal axis of the tubular sheath of the condom (see figs.4,5, and 10) and the collar comprises an internal diameter adapted to receive the male sexual organ and, where the collar comprises a barricade (circular surface of 25,35,74) that is fully capable of covering the vulva or anus during coitus, such that the condom is prevented from being forced into said orifice of a passive sexual participant during sexual intercourse, and where the collar fully capable of providing female clitoral stimulation. Reddy however lacks a tapered neck at the open, proximal end and where the tapered neck allows the condom to more readily be retained with muscle contraction by a passive user within a sexual orifice. However, Schwartz teaches a condom with a tapered, narrow neck (fig. 4, 22). Therefore, it would have been obvious to one or ordinary skills in the art at the time the invention was made to modify Reddy in order to provide a tapered, narrow proximal end for the purposes assisting erectile function as taught by Schwartz (see col.5 lines 1-10). Tapered narrow end as taught by Schwartz is fully capable of allowing condom to more readily be retained with muscle contraction by a passive user with a sexual orifice.

As to claim 4, Reddy's collar (25, 35, and 74,112) does not contain any rings or other metal to keep the collar at the surface of the entrance to a vagina or anus.

As to claim 5, Reddy discloses the collar at the open proximal end is larger than the diameter of the cylindrical wall section of the condom (see figs, 4,5,10, and 13c), such that the collar is retained outside the vagina or anus during sexual intercourse, and where the tubular sheath portion is of a size to form a loose fit around the penis (Reddy teaches the diameter of the tubular member can be varying sizes (col.9 lines 10-15). Whether the condom is loosely fitted would depend on its size chosen by the user. It is inherent for a user to choose a size that would loosely fit them in order to prevent bursting/breaking of the condom). Flexible, semi-rigid wall material as applied to claim 1 is fully capable of facilitating insertion into the sexual orifice of the passive user.

As to claim 9, Reddy lacks where the second means for retaining and securing comprises a shape-retaining, tubular shaft with a graduated diameter whereby the shape-retaining, tubular sheath is tapered and contoured to more readily be retained with muscle contraction by a passive user within a sexual orifice. However, Schwartz teaches graduated diameter of tubular sheath from closed end (fig.4, 10) to a tapered neck (fig.4, 22). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Reddy's tubular sheath (i.e. 32) in order to provide graduated diameter for the purposes of maintaining erection by imparting an external pressure onto the penis to impede venous blood flow therefrom as taught by Schwartz (see col.5 lines 6-10).

As to claim 13, Reddy teaches a tapered, narrow, neck section as applied for claim 9. The tapered neck inherently allows the device to have a diameter sufficient to be more readily retained with muscle contraction within the sexual orifice by the passive user. Reddy teaches the outwardly extending collar comprising means (26/36) for radially stretching the open end, the collar having a first diameter (in communication with the open end 24/34) and a second diameter (outer diameter of the flange 25/35). Figures 4 and 4 shows the second diameter larger than said first diameter, the strap (36/26) integrally formed of and in communication with the peripheral edge of the collar.

Claims 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy US 5,168,881 in view of Pasczuk et al. US 555,799,657.

As to claim 8, Reddy lacks a semicircular, flexible, elastic, radially extending retaining strap which is circumferentially and contiguously formed adjacent to and in communication with the outer edge of the collar at the proximal, open end, said retaining strap adapted to be stretched away from the collar to be arranged around the scrotum and testicles of the active male wearer and retained there snuggly, thereby providing a securing mechanism in communication with the shape-retaining, tubular sheath for securing the device to the active male wearer, and, where the retaining strap comprises a stretchable material coupled to the collar at the proximal end thereof. However, Pasczuk teaches claimed retaining strap (fig.5, 4) that stretches away from a collar (fig.5, 10) which is semi-circular (Pasczuk in figure 5 shows the retaining strap is integral to a collar (10). The retaining strap is separated from the collar (10) by a semi-circular cut (see fig.5). Thus Pasczuk teaches semi-circular retaining strap). Therefore, it would have been obvious to modify Reddy's strap (27,37) in order to provide a retaining strap as claimed for the purposes of allowing condom to retain onto the wearer without the risk of withdrawal upon loosing erection as taught by Pasczuk (see col.3 lines 26-31). Reddy and Pasczuk is silent on the construction material for the retaining strap. However, Reddy teaches the condom can be made from synthetic material such as polyurethane, polyvinylchloride, silicone elastomer, etc. (col.7 lines 14-16), these material of choice read on claimed "group consisting of biocompatible polymers, thermoplastic elastomer, silicone rubber latex or comparable combinations and derivatives thereof". It would have been obvious to one of ordinary skill in the art to make the retaining strap with the same material as the condom because using same material to make different parts of condom would not require changing and choosing different composition of material for different parts, thus, allow more efficient way to make condom in one shot molding process.

As to claim 11, Reddy in view of Pasczuk teaches the first means for retaining and securing is a strap (retaining strap) as applied for claim 8. Pasczuk in figure 5 shows the strap (4) shares a common edge adjacent to and in communication with the collar (10) and the strap is formed with the collar so as to provide a single piece condom. Pasczuk in figure 2 shows the retaining strap formed of a common stretchable material with the collar and elongated in the direction of an active male wearer's scrotum, whereby said strap is tightly encircling the scrotum of the active male wearer, and, wherein the strap is stretched around the testicles of the active male wearer. The positioning of the strap over the scrotum and testicles as shown in figure 2 inherently allows blood flow away from the penis when it is erect, which in turn causes the erection to be substantially maintained for an extended period of time.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy US 5,168,881 in view of Pasczuk et al. US 555,799,657 in view of Alla et al US 5,992,415 and in view of Spery US 5,598,852.

As to claim 10, Reddy's condom is large enough to cover the penis of any length and girth, including the base of the penis shaft (see disclosure of varying length of condom in col.9 lines 10-15). Reddy lacks the strap is harnessed snuggly around the scrotum and retained by the posterior of the scrotum. However, Reddy in view of Pasczuk teaches claimed harness (retaining strap) and collar as applied for claim 8. Reddy however lacks a seminal reservoir. However, such reservoir device used in combination of unisex condom is known in the art. Alla teaches reservoir (see fig.2, 28) configured to fit into the closed end of the condom, which is capable of retaining fluid in addition to ease installation and retention of the condom (see Alla, cols.2-3). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the invention of Reddy in order to include a reservoir for the purposes of easing the insertion of condom and retaining fluid.

Reddy further lacks an insertion applicator. However, Spery teaches an applicator (insertion element). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Reddy in order to provide an applicator for the purposes of facilitating the insertion of condom in the passive sexual organ as taught by Spery (see col.4 lines 17-20).

Claims 14 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy US 5,168,881 in view of Alla et al. US 5,992,415.

As to claim 14, Reddy lacks a reservoir. Alla teaches the reservoir as applied for claim 10. Alla in figure 3 shows the reservoir disposed in a substantially closed compartment inside the closed distal end of the condom, wherein the reservoir consists of the closed distal end and defined by a flange (25), where the flange is a circumferential piece of the condom, with a hole in the middle (area between the tapered neck of 25 has hole leading to the foam 32), funneled down toward the distal end of the condom, such that when semen is ejaculated into the reservoir the downward direction of the flange is thereby serving to trap the semen (via 32) in the reservoir and prevent its escape and subsequent backflow.

As to claim 15, Alla teaches foam (32), or otherwise sponge-like, absorbent, insert, whereby said insert will absorb transmission of bodily fluids propelled in a distal direction and further prevent backflow and spillage thereof.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy US 5,168,881 in view of Pasczuk et al. US 555,799,657 in view of Schwartz US 5,513,652 and in view of Alla et al US 5,992,415.

As to claim 16, Reddy discloses a collar (25/35) with first (portion in contact with the open end of the tubular sheath 22/32) and second portion (outermost diameter of 25/35), and figures 4 and 5 show that the diameter of the collar are graduated to greater than the diameter of the first portion. Pasczuk teaches retaining strap as applied for claim 8. Pasczuk in figure 5 shows the retaining strap is integral to a collar (10). The retaining strap is separated from the collar (10) by a semi-circular cut (see fig.5). Thus Pasczuk teaches semi-circular retaining strap. Schwartz teaches graduated diameter of tubular sheath as applied for claim 9. Alla teaches reservoir as applied for claim 10.

As to claim 17, Reddy discloses said length of the tubular section (see fig.16) is sufficient to maintain said collar in contact with a vulva or an anus, whereby the tubular sheath forms a shape-retaining lining of the vaginal cavity or of the rectum (see fig.16).

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy US 5,168,881 in view of Spery US 5,598,852.

As to claim 18, Reddy lacks a piloting assembly device. However, Spery teaches the piloting assembly device (insertion element) as applied for claim 18. Spery further teaches the applicator of the type comprising a rigid, shape-retaining plastic or polymer form (col.4 lines 23-26), the insertion applicator being in co-axial communication with the tubular sheath (see fig.5c), whereby easy insertion is made possible for the passive user, the condom adapted to be inserted into a sexual orifice of passive participant such as the vagina or the anus via the closed distal end, whereby the condom may function as an internal female or passive-user device (see fig.5c).

As to claim 19, Spery teaches the piloting assembly device is biocompatible (col.4 lines 23-26).

As to claim 20, Spery teaches the piloting assembly is not limited to biocompatible (see col.4 lines 26-41).

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUMAYA B. ALI whose telephone number is (571)272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

2/1/2008
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